

CLAIMS

We claim:

1. An oral dosage form configured to provide controlled release of a liquid active agent formulation, the dosage form comprising:
 - 5 a reservoir formed of a material that is impermeable to the passage of water, the liquid active agent formulation being contained within the reservoir; and
a delivery means for expelling the liquid active agent formulation from oral dosage form at a controlled rate positioned at least partially within the reservoir.
2. The oral dosage form of claim 1, wherein the reservoir is formed of a single
10 layer of material comprising a water impermeable polymer.
3. The oral dosage form of claim 1, wherein the reservoir is formed of a single layer of material comprising a water impermeable polymer selected a group of water impermeable polymers consisting of linear polycondensation resins, condensation polymerized resins, addition polymerized resins, resins of phthalic anhydrides,
15 polyvinyl resins such as polyethylene, polypropylene and their copolymers, polymer resins of methacrylic acid esters and acrylic acid esters, polycaprolactone, and copolymers of polycaprolactone with dilactide, diglycolide, valerolactone or decalactone.
4. The oral dosage form of claim 1, wherein the reservoir is a multilayer reservoir
20 comprising a water permeable material and a water impermeable subcoat provided over the water permeable material.
5. The oral dosage form of claim 1, wherein the reservoir is a multilayer reservoir comprising a hydrophilic polymer material and a water impermeable subcoat provided over the hydrophilic polymer material.

6. The oral dosage form of claim 1, wherein the reservoir is a multilayer reservoir comprising a hydrophilic polymer material and a water impermeable subcoat provided over the hydrophilic polymer material, wherein the hydrophilic polymer material is selected from a polysaccharide material and a poly(vinylalcohol-co-ethylene glycol).
- 5 7. The oral dosage form of claim 6, wherein the polysaccharide material is selected from a group consisting of hydroxypropylmethyl cellulose (HPMC), methylcellulose, hydroxyethyl cellulose (HEC), and hydroxypropyl cellulose (HPC).
8. The oral dosage form of claim 1, wherein the reservoir is a multilayer reservoir comprising a water permeable material and a water impermeable subcoat provided over
10 the water permeable material, the water impermeable subcoat being formed of a water impermeable latex material.
9. The oral dosage form of claim 1, wherein the reservoir is a multilayer reservoir comprising a water permeable material and a water impermeable subcoat provided over the water permeable material, the water impermeable subcoat being formed of a
15 polymethylacrylate latex material.
10. The oral dosage form of claim 1, wherein the reservoir is a multilayer reservoir comprising a gelatin material and a water impermeable subcoat provided over the gelatin material.
11. The oral dosage form of claim 1, wherein the reservoir includes an opening and
20 an expandable osmotic composition positioned within the opening, with the reservoir and the opening being configured such that the expandable osmotic composition is not completely encapsulated by the reservoir.

12. The oral dosage form of claim 1, wherein the delivery means for expelling the liquid active agent formulation from oral dosage form at a controlled rate comprises an expandable osmotic composition positioned within the reservoir such that a portion of the expandable osmotic composition is not enclosed by the reservoir.
- 5 13. An oral dosage form comprising:
- a reservoir formed of a water impermeable material, the reservoir comprising an opening;
- a liquid active agent formulation contained within the reservoir;
- an expandable osmotic composition positioned within the opening of the
- 10 reservoir such that at least a portion of the expandable osmotic composition is not enclosed by the reservoir;
- a semipermeable membrane formed over the portion of the expandable osmotic composition that is not enclosed by the reservoir; and
- an exit orifice.
- 15 14. The oral dosage form of claim 13, wherein the reservoir is formed of a single layer of water impermeable material.
15. The oral dosage form of claim 13, wherein the reservoir is formed of a single layer of a water impermeable polymer material.
16. The oral dosage form of claim 13, wherein the reservoir is formed of a single
- 20 layer of water impermeable polymer material selected from a group consisting of linear polycondensation resins, condensation polymerized resins, addition polymerized resins, resins of phthalic anhydrides, polyvinyl resins such as polyethylene, polypropylene and their copolymers, polymer resins of methacrylic acid esters and acrylic acid esters,

polycaprolactone, and copolymers of polycaprolactone with dilactide, diglycolide, valerolactone or decalactone.

17. The oral dosage form of claim 13, wherein the reservoir is a multilayer reservoir comprising a water permeable material and a water impermeable subcoat provided over
5 the water permeable material.

18. The oral dosage form of claim 13, wherein the reservoir is a multilayer reservoir comprising a hydrophilic polymer material and a water impermeable subcoat provided over the hydrophilic polymer material.

19. The oral dosage form of claim 13, wherein the reservoir is a multilayer reservoir
10 comprising a hydrophilic polymer material and a water impermeable subcoat provided over the hydrophilic polymer material, wherein the hydrophilic polymer material is selected from a polysaccharide material and a poly(vinylalcohol-co-ethylene glycol).

20. The oral dosage form of claim 13, wherein the polysaccharide material is selected from a group consisting of hydroxypropylmethyl cellulose (HPMC),
15 methylcellulose, hydroxyethyl cellulose (HEC), and hydroxypropyl cellulose (HPC).

21. The oral dosage form of claim 13, wherein the reservoir is a multilayer reservoir comprising a water permeable material and a water impermeable subcoat provided over the water permeable material, the water impermeable subcoat being formed of a water impermeable latex material.

20 22. The oral dosage form of claim 13, wherein the reservoir is a multilayer reservoir comprising a water permeable material and a water impermeable subcoat provided over the water permeable material, the water impermeable subcoat being formed of a polymethylacrylate latex material.

23. The oral dosage form of claim 13, wherein the reservoir is a multilayer reservoir comprising a gelatin material and a water impermeable subcoat provided over the gelatin material.
24. The oral dosage form of claim 13, wherein the semipermeable membrane
5 extends over an outer surface of the reservoir.
25. A method for making an oral dosage form, the method comprising:
providing a reservoir formed of a water impermeable material and including an opening;
loading the reservoir with a liquid active agent formulation;
10 positioning an expandable osmotic composition within the opening included in the reservoir such that a portion of the expandable osmotic composition remains exposed;
providing a semipermeable membrane over at least the exposed portion of the expandable osmotic composition; and
15 creating an exit orifice that allows delivery of the liquid active agent formulation from the dosage form.
26. The method according to claim 25, wherein providing a reservoir includes providing a reservoir formed of a single layer of material.
27. The method according to claim 25, wherein providing a reservoir includes
20 providing a reservoir formed of a water impermeable polymer material.
28. The method according to claim 25, wherein providing a reservoir includes providing a reservoir formed of a water impermeable polymer material selected from linear polycondensation resins, condensation polymerized resins, addition polymerized resins, resins of phthalic anhydrides, polyvinyl resins such as polyethylene,

polypropylene and their copolymers, polymer resins of methacrylic acid esters and acrylic acid esters, polycaprolactone, and copolymers of polycaprolactone with dilactide, diglycolide, valerolactone or decalactone.

29. The method according to claim 25, wherein providing a reservoir includes
5 providing a multilayer reservoir comprising a water permeable material and a water impermeable subcoat provided over the water permeable material.

30. The method according to claim 25, wherein providing a reservoir includes providing a multilayer reservoir comprising a hydrophilic polymer material and a water impermeable subcoat provided over the hydrophilic polymer material.

10 31. The method according to claim 25, wherein providing a reservoir includes providing a multilayer reservoir comprising a hydrophilic polymer material and a water impermeable subcoat provided over the hydrophilic polymer material, wherein the hydrophilic polymer material is selected from a polysaccharide material and a poly(vinylalcohol-co-ethylene glycol).

15 32. The method according to claim 31, wherein providing a multilayer reservoir comprising a hydrophilic polymer material comprises providing a multilayer reservoir including a hydrophilic polymer material selected from a group consisting of hydroxypropylmethyl cellulose (HPMC), methylcellulose, hydroxyethyl cellulose (HEC), and hydroxypropyl cellulose (HPC).

20 33. The method according to claim 25, wherein providing a reservoir includes providing a multilayer reservoir comprising a water permeable material and a water impermeable subcoat provided over the water permeable material, the water impermeable subcoat being formed of a water impermeable latex material.

34. The method according to claim 25, wherein providing a reservoir includes providing a multilayer reservoir comprising a water permeable material and a water impermeable subcoat provided over the water permeable material, the water impermeable subcoat being formed of a polymethylacrylate latex material.
- 5 35. The method according to claim 25, wherein providing a reservoir includes providing a multilayer reservoir comprising a gelatin material and a water impermeable subcoat provided over the gelatin material.
36. The method according to claim 25, wherein providing a semipermeable membrane comprises providing a semipermeable membrane that extends over an outer
- 10 surface of the reservoir.